



University of
Salford
MANCHESTER

Observations on surveillance imaging after endovascular sealing of abdominal aortic aneurysms with the Nellix system

McWilliams, RG, Fisher, RK, England, A and Torella, F

<http://dx.doi.org/10.1177/1526602815582209>

| | |
|-----------------------|--|
| Title | Observations on surveillance imaging after endovascular sealing of abdominal aortic aneurysms with the Nellix system |
| Authors | McWilliams, RG, Fisher, RK, England, A and Torella, F |
| Type | Article |
| URL | This version is available at: http://usir.salford.ac.uk/35051/ |
| Published Date | 2015 |

USIR is a digital collection of the research output of the University of Salford. Where copyright permits, full text material held in the repository is made freely available online and can be read, downloaded and copied for non-commercial private study or research purposes. Please check the manuscript for any further copyright restrictions.

For more information, including our policy and submission procedure, please contact the Repository Team at: usir@salford.ac.uk.

Observations on surveillance imaging after endovascular sealing of abdominal aortic aneurysms

Robert K Fisher¹ MD, FRCS

Richard G McWilliams¹ FRCR EBIR,

Andrew England² Ph.D

*Francesco Torella¹ MD, FRCS

Liverpool Vascular and Endovascular Service¹, Royal Liverpool University Hospitals, Liverpool, UK

Directorate of Radiography², University of Salford, Manchester, UK

*corresponding author

8C Link, Royal Liverpool University Hospital, Prescot Street, L7 8XP, Liverpool, UK

e-mail: f.torella@liverpool.ac.uk; tel: +44 1517063481

Short title: Post-EVAS surveillance findings

The authors declare no conflict of interest and no sources of funding.

Abstract

Purpose. Endovascular aneurysm sealing (EVAS), performed with the Nellix® endoprosthesis, is a new technique to treat patients with infrarenal abdominal aortic aneurysm. We describe findings on post-EVAS imaging, discuss their interpretation, and consider their potential implications on EVAS planning and performance.

Methods. We performed a retrospective review of perioperative imaging in consecutive patients undergoing elective EVAS at our centre. We systematically reviewed perioperative imaging specifically looking for endobag collapse, aortic thrombus compression and aortic wall disruption, according to definitions set a priori.

Results. Between December 2013 and November 2014, we performed EVAS in 30 patients, with no perioperative mortality and no endoleaks. Endobag collapse, aortic thrombus compression and aortic wall disruption were observed in 12, 15 and one patient respectively. Endobag collapse could, potentially, result in type II endoleak, if occurring near a patent side branch. Thrombus compression affects the accuracy of preoperative volume measurements in predicting the amount of polymer needed to perform EVAS. Aortic wall disruption could, potentially, result in intraoperative haemorrhage.

Conclusions. Our observations and their potential implications should help clinicians in planning and performing EVAS, as well as in interpreting postoperative imaging.

Keywords. Endovascular sealing, abdominal aortic aneurysm, Nellix®, aortic thrombus, aortic aneurysm repair.

Introduction

Endovascular sealing of abdominal aortic aneurysms (EVAS), which is performed with the Nellix® (Endologix Inc., Irvine, California, USA) endoprosthesis is a new technique to treat patients with abdominal aortic aneurysms, based on different principles than those relied upon by open or endovascular aneurysm repair. During EVAS, the lumen of the aneurysm is filled with a bio-compatible polymer (polyethylene glycol diacrylate hydrogel), contained within two endobags, which is injected in liquid form and solidifies in situ within five minutes. Within each endobag, there is a 10 mm, balloon expandable covered stent that preserves flow into each common iliac artery. The Nellix® endoprosthesis gained Conformite Europeene (CE) marking in 2013, therefore experience with EVAS is still very limited. Currently there are only nine published original studies on EVAS¹⁻⁹, including two case reports⁶⁻⁷ and one in vitro study⁵. The aim of this paper is to report our observations on perioperative imaging of specific findings related to the EVAS technique.

Methods

EVAS was introduced into our practice in December 2013, under strict internal regulatory conditions, which included meticulous prospective audit of results. Technical suitability for EVAS was determined by two of three senior clinicians (the authors) on arterial phase computed tomography images and confirmed by a multidisciplinary team reviewing, weekly, all prospective elective patients under consideration for aortic aneurysm repair. The EVAS technique has been described elsewhere^{1,9}. In brief, two suitable Nellix® catheters are positioned in the infrarenal aorta and their respective stents inflated, simultaneously, to a pressure of 7 atm. The two endobags, whose filling volume had been estimated on preoperative imaging, are then simultaneously filled with a saline solution up to a pressure of 180 mmHg. The saline solution is then removed from the endobags, its volume precisely measured and replaced by the polymer, again up to a pressure of 180 mmHg. Prior to endobag inflation, it is routine practice to create a “vacuum” in the endobags by aspirating all air contained in them with a large syringe. The polymer is injected by means of a dispenser in 3 ml increments until the desired pressure is achieved. After the polymer fill, the stent balloons are re-inflated to a pressure of 10 atm, and left inflated until the polymer is cured. The balloons are deflated, the catheters removed and the stent post-dilated with shorter (typically 10x60 or 10x40 mm) balloons at 12 atm.

Our follow up protocol includes post-operative imaging by plain abdominal radiographs on day 1, duplex ultrasound and arterial phase computed tomography at one month, followed by yearly plain abdominal radiographs and duplex ultrasound scans, with additional cross-sectional imaging reserved for specific cases, or for cases with suspected complications. All post-operative images were reported by a senior clinician (RGM) and any unexpected findings recorded and discussed at the weekly multidisciplinary meeting. These included three specific observations. Firstly, air in the endobags on post-operative radiographs with subsequent partial collapse of the endobag after absorption of the air. Secondly, evidence of compression of the aortic thrombus by the endobags.

Lastly, evidence of asymptomatic post-EVAS aortic wall disruption. For the purpose of this study, two of the authors (FT, RGM) further reviewed all the perioperative images to determine the incidence of these three observations using specific definitions.

The observation of air in the endobags was made when there was a fluid level on a cross-table lateral abdominal radiograph within the aortic contour and considered unrelated to bowel loops. Endobag collapse was defined as focal change in outline in axial images in one or both endobags which did not correspond to the pre-operative contour of the thrombus or aortic wall.

Thrombus compression was defined as 5mm or greater reduction in the maximum thickness of the aortic mural thrombus after EVAS comparing equivalent axial CT images.

Aortic wall disruption was defined, by consensus opinion based on comparison of pre and post-EVAS CT images, as a discernible gap in a previously continuous segment of calcification with or without extrusion of thrombus or adventitial haematoma.

Results

Nineteen men and 11 women with a median (IQR) age of 79 (73-83) years underwent EVAS over a one-year period. All procedures were performed to treat primary infrarenal aortic aneurysms, in one a single stent and endobag was used in a uni-iliac configuration. The median (IQR) aneurysm maximum diameter was 58 (57-60) mm. There were no perioperative deaths and all aneurysms were successfully excluded, with no endoleaks.

All patients underwent post-operative plain radiography and twenty nine underwent 1-month CT scans. One patient died ten weeks after EVAS from unrelated causes without having undergone a post-operative surveillance CT scan. The median (IQR) interval between the pre-operative CT and EVAS was 109 (51-162) days and between EVAS and the first post-operative CT was 31 (30-37) days.

Endobag air and collapse

Eleven patients were noted to have an obvious air-fluid level on the lateral abdominal radiograph, which persisted on the 1-month CT in three cases (figure 1). An additional five patients, without definite air on the radiographs, were noted to have air in one or both endobags on the 1-month CT. Twelve patients displayed endobag collapse (figure 2) without any evidence of associated endoleak.

Thrombus compression

Aortic thrombus in excess of 5 mm thickness on pre-operative axial CT images was noted in 25 of the 29 patients who underwent both pre- and post-operative CT. In all but 9 patients there was a small increase in aortic diameter between the pre-operative and post-operative CT, which we attributed to interval growth. The median (IQR) difference in maximum aortic diameter for the whole group was 1 (0-2) mm. A reduction of the thickness of the aortic thrombus of at least 5 mm was noted in 15 cases (figure 3).

Aortic wall disruption

Aortic wall disruption was noted in only one patient (fig. 4). There was no aortic thrombus compression in this case, and the maximum aneurysm diameter increased by 5mm between the pre-operative and post-operative CT scans, which were performed 153 days apart.

Discussion

We describe three findings on post-operative surveillance imaging after EVAS which are specific to the technique and have several potential implications.

Endobag air and collapse

Despite adherence to the instructions for use during preparation and deployment of the Nellix system, some air may remain within the endobags. Upon filling of the endobags this air lies anterior to the polymer as illustrated on post-operative imaging in a proportion of cases. Our interpretation of endobag collapse is that this air resorbs with time allowing the anterior margin of the endobag to settle onto the cured polymer. Although this may be a benign issue, the formation of a secondary type II endoleak from the inferior mesenteric artery, the very complication that EVAS is supposed to minimise, remains a theoretical possibility after reabsorption of large volumes of air (figure 5).

Aortic thrombus compression

The polymer fill volume is calculated on pre-operative imaging by measuring the aorto-iliac lumen and subtracting, from this, the volume of the stents. The consistency of aortic thrombus may vary between patients, thus, in aneurysms with compressible thrombus, larger volumes than anticipated will be needed to reach the target pressure. Our findings indicate that there is thrombus compression of at least 5mm in approximately 60% of patients whose aneurysm contain thrombus. The primary implication of this finding is that an increased polymer fill volume may be required compared to the pre-operative estimation. This must be considered in the pre-operative planning process and stresses the importance of the saline pre-fill in determining the actual volume required for successful sealing. This step is considered optional in the instruction for use¹¹, however, in view of our findings, it should be seen as mandatory. A further potential complication of thrombus compression is embolic phenomena through aortic side branches.

We recognise that there was a temporal delay between the pre-operative CT scan and EVAS, during which the thrombus volume may have changed. It is notable, however, that the aneurysm diameter only increased by a mean of 1mm between the pre- and post-operative CT scans.

Aortic wall breach

Although we observed a breach in the aortic wall in only one case, this is a potentially serious consequence unique to the EVAS technique. This complication may occur during the saline pre-fill or the polymer fill. One might assume that occurrence during the former may have greater clinical consequences as the endobags will be emptied prior to polymer fill. Our case was asymptomatic and only detected on post-operative CT. Aortic wall breach may occur because of excessive inflation pressure, uneven distribution of pressure during the filling process, or pre-existing weakness of the aortic wall.

Conclusion

EVAS is a new technique to treat abdominal aortic aneurysms and promises to reduce the incidence of late complications such as type II endoleak. It may expand the use of endovascular therapy for this condition^{1-2,4,6-8}. Its effectiveness may only be confirmed after many years of use, and following appropriate longitudinal and comparative trials. In the meantime, its safety remains under scrutiny. As worldwide experience with the technique is extremely limited, it is likely that many “unusual” post-operative findings, on routine imaging, will be detected. Some of these findings could, in some cases, have clinical consequences. Clinicians involved in EVAS have a duty to report any such findings. This approach may be vital to guarantee the safety of EVAS and, hopefully, unveil its effectiveness in due course.

References

1. Donayre CE, Zarins CK, Krievins DK, Holden A, Hill A, Calderas C, Velez J, White RA. Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair. *J Vasc Surg* 2011;53:574-82.
2. Krievins DK, Holden A, Savlovskis J, Calderas C, Donayre CE, Moll FL, Katzen B, Zarins CK. EVAR using the Nellix sac-anchoring endoprosthesis: treatment of favourable and adverse anatomy. *Eur J Vasc Endovasc Surg* 2011;42:38-46.
3. Kisis K, Krievins D, Naskovica K, Gedins M, Savlovskis J, Ezite N, Lietuvietis E, Zarins K. Quality of life after endovascular abdominal aortic aneurysm repair: Nellix sac-anchoring endoprosthesis versus open surgery. *Medicina* 2012;48:286-91
4. Kartikhesalingam A, Cobb RJ, Khoury A, Choke EC, Sayers RD, Holt PJ, Thompson MM. The morphological applicability of a novel endovascular aneurysm sealing (EVAS) system (Nellix) in patients with abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg* 2013;46:440-5
5. Niepoth NN, de Bruin JL, Lely RL, Wisselink W, de Vries JP, Yeung KK, Blankensteijn JD. In vitro feasibility of a sac-sealing endoprosthesis in a double chimney graft configuration for juxtarenal aneurysm. *J Endovasc Ther* 2014;21:529-37.
6. Malkawi AH, de Bruin JL, Loftus IM, Thompson MM. Treatment of a juxtarenal aneurysm with the Nellix endovascular sealing system and chimney stent. *J Endovasc Ther* 2014;21:538-40.
7. Dijkstra ML, Lardenoye JW, van Oostayen JA, Zeebregst CJ, Reijnen MM. Treatment of a juxtarenal aneurysm with the Nellix endovascular sealing system and chimney stent. *J Endovasc Ther* 2014;21:541-7.
8. Bockler D, Reijnen MM, Krievins D, Peters AS, Hayes P, De Vries JP. Use of the Nellix EVAS system to treat post-EVAR complications and to treat challenging infrarenal necks. *J Cardiovasc Surg* 2014;55:601-12.

9. Bockler D, Peters AS, Pfeiffer S, Kovacs B, Geisbusch P, Bischoff MS, Muller-Eschner M, Pfeiffer S. Nellix Endovascular Aneurysm Sealing (EVAS) – eine neue Technologie zur endovaskulären Ausschaltung infrarenaler Aortenaneurysmen. Zentralbl Chir 2014;139:562-8.
10. Coulston J, Baigent A, Selvachandran H, Jones S, Torella F, Fisher R. the impact of endovascular aneurysm repair on aortoiliac tortuosity and its use as a predictor of iliac limb complications. J Vasc Surg 2014;60:585-9.
11. Nellix, Instructions For Use, Copyright 2013, Endologix

Figure legends

1. Cross table lateral abdominal radiograph after EVAS showing air anteriorly in the endobag (white arrow)
2. Pre-operative and post-operative axial CT images in the same patient as figure 1 showing collapse of the endobag anteriorly (white arrow) after air reabsorption. There is no evidence of type 2 endoleak from the inferior mesenteric artery which arises at this level.
3. Axial CT images of the aorta of the same patient at the same level a) before and b) after EVAS. Note the much reduced thrombus-filled area in the postoperative image.
4. Axial CT images before and after EVAS. Before EVAS there is continuous aortic wall calcification along the left margin of the aneurysm. After EVAS there is a large breach of this calcification (white arrows) with thrombus seen outside of this (curved white arrow).